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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/073,625	02/11/2002	Joseph R. Lakowicz	UMARY1	4325
23373	7590	12/10/2003	EXAMINER	
SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. WASHINGTON, DC 20037			CHAKRABARTI, ARUN K	
			ART UNIT	PAPER NUMBER
			1634	

DATE MAILED: 12/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

*Restart
(Revo not entered)*

Office Action Summary

Application No.
10/073,625

Applicant(s)
Lakowicz

Examiner
Arun Chakrabarti

Art Unit
1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 26, 2003
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 10-14, and 28-82 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 10-14, and 28-82 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Detailed Action

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DETAILED ACTION

Current Status of the Application

1. Applicant's amendment filed on September 26, 2003, has been entered. Claims 3-9, and 15-27 have been canceled without prejudice towards further prosecution. New claims 28-82 have been added. Claims 1-2, 10-14, and 28-82 are currently pending in this application.

Election/Restriction

2. Applicant's election of Group I, without traverse, is hereby acknowledged.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 28-45, and 67-82 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 28-45, and 67-82 are rejected over the recitation of the negative limitations "an extrinsic fluorescent marker is not a part of the system" (See MPEP 2173.05 (I)) -- "Any negative limitation or exclusionary proviso must have basis in the original disclosure. See *Ex parte Grasselli*, USPQ 393 (Bd. App. 1983), *aff'd mem.*, 738 F.2d 453 (Fed. Cir. 1984). The mere

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absence of a positive recitation is not basis for an exclusion. Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement". In the instant application, negative limitations inserted in the amended claims do not have any expressed basis in the original specification (page 13, lines 19-21, and at page 24, line 27 to page 25, line 5) as mentioned by the applicant in the Remarks section, page 11, line 1.

5. Claims 1-2, and 10-14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The following limitations have not been found in the specification of the instant application (page 3, lines 17-19) as mentioned by the applicant in the Remarks Section, page 10, line 9 and is therefore NEW MATTER:

"Single metal particle" - claims 1, 10, 11, 13, and 14

Claims which directly or indirectly depend from the above listed claims also contain the NEW MATTER due to said dependance.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-2, and 10-14 are rejected under 35 U.S.C. 102 (b) as being anticipated by Schalkhammer et al. (U.S. Patent 5,866,433) (February 2, 1999).

Schalkhammer et al. teaches a composition of matter comprising: a biomolecule in combination with a metal particle, wherein the metal particle and the biomolecule are positioned at a distance apart sufficient to adjust intrinsic emission of electromagnetic radiation from the biomolecule in response to an amount of exciting electromagnetic radiation (Abstract, Figures 1-4 and Column 1, lines 7-25, and Column 3, line 4 to Column 5, line 4 and Claims 3-18).

Schalkhammer et al. teaches a composition, wherein the biomolecule comprises an oligonucleotide, nucleotide or nucleoside, purine or pyrimidine, and a nucleic acid (Column 3, lines 63-67 and claim 16).

Schalkhammer et al. teaches a composition, wherein the distance of the metal particle from the biomolecule is less than 10 nm (Column 4, lines 46-52 and Figures 1-4) which is equal to less than 100 Angstrom but falls in the range of about 50 Angstrom and therefore meets the requirement of the claim 10.

Schalkhammer et al. teaches a composition, wherein the metal particle comprises a noble metal selected from silver and gold (Column 3, lines 33-45 and Claim 14).

Schalkhammer et al. teaches a composition, wherein the metal particle is sub-wavelength in size (Column 3, lines 55-62 and Claim 15).

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Schalkhammer et al teaches a composition, wherein the biomolecule is linked to the metal particle (Column 4, lines 32-45 and Claim 3).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 46-66 are rejected under 35 U.S.C. 103(a) as being obvious over Schalkhammer et al. (U.S. Patent 5,866,433) (February 2, 1999) in view of Natan et al. (U.S. Patent 6,149,868) (November 21, 2000).

Schalkhammer et al teach the method of claims 1-2, and 10-14 as described above.

Schalkhammer et al. teaches a composition, wherein the biomolecule comprises a protein and an amino acid (Column 3, lines 63-67 and claim 16).

Schalkhammer et al. teaches a composition, wherein the biomolecule comprises a lipid (Column 3, lines 63-67 and claim 16).

Schalkhammer et al. teaches a composition, wherein the biomolecule comprises a sugar moiety (Column 5, lines 1-4).

Schalkhammer et al teaches a system comprising:

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a solid support, wherein the solid support is coated with metal particles (Figures 1-4); and

a matrix having an array of biomolecules attached to the support such that when a labeled probe hybridizes to the biomolecules, the fluorescence of the labeled probe increases in response to an amount of exciting radiation (Figures 1-4 and Claims 1-2).

Schalkhammer et al. teaches a system comprising: a biomolecule in combination with a metal surface, wherein the metal surface and the biomolecule are positioned at a distance apart sufficient to adjust intrinsic emission of electromagnetic radiation from the biomolecule in response to an amount of exciting electromagnetic radiation (Abstract, Figures 1-4 and Column 1, lines 7-25, and Column 3, line 4 to Column 5, line 4 and Claims 3-18).

Schalkhammer et al does not teach a system comprising a colloidal suspension of one or more metal particles.

Natan et al. teaches a system comprising a colloidal suspension of one or more metal particles (Abstract and Column 1, lines 36-65 and Column 5, lines 40-56).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute a system comprising a colloidal suspension of one or more metal particles of Natan et al. in the system of Schalkhammer et al., since Natan et al states, "In yet another embodiment, detection is accomplished at extremely low analyte concentrations (Abstract, lines 12-13)". By employing scientific reasoning, an ordinary practitioner would have been motivated to combine and substitute a system comprising a

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colloidal suspension of one or more metal particles of Natan et al. in the system of Schalkhammer et al. in order to improve the process for determining the concentration of biomolecules and also in order to achieve the express advantages, as noted by Natan et al., of an invention which provides a system wherein detection is accomplished at extremely low analyte concentrations.

Response to Amendment

10. In response to amendment, previous 102(b) rejection has been maintained properly and a new 112 (first) and 103(a) rejections have been included.

Response to Arguments

11. Applicant's arguments with respect to all pending claims have been considered but are moot in view of the new ground(s) of rejection.

Applicant's argument to withdraw 102(b) rejection has been considered but has not been found persuasive.

Applicant argues that Schalkhammer et al reference does not teach the single metal particle of the claimed invention. Applicant argues that the word "single metal particle" was not found in Schalkhammer reference and only the word "multiple metal particles" are found. Applicant argues that because Schalkhammer et al has a preferred embodiment of multiple metal particles, Schalkhammer et al is limited to the preferred embodiment. This argument is not persuasive. As MPEP 2123 states "Disclosed examples and preferred embodiments do not

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constitute a teaching away from a broader disclosure or nonpreferred embodiments. In *re Susi*, 169 USPQ 423 (CCPA 1971)." MPEP 2123 also states "A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill in the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 10 USPQ2d 1843 (Fed. Cir. 1989)." It is clear that simply because Schalkhammer et al has a preferred embodiment, this embodiment does not prevent the reference from suggesting broader embodiments in the disclosure and that this does not constitute a teaching away. Although Schalkhammer et al reference uses multiple metal particles to detect the biomolecules, the property of detecting a biomolecule by electromagnetic radiation is inherently present in each single of this chemically and structurally identical molecule. For example, Schalkhammer et al teaches, "As an alternative, the island layer may be produced or modified by the attachment of metallic particles or islands to the substrate, or by removing excess metal from the substrate layer, thereby forming islands or changing their number or size, in which way the desired mass thickness may be obtained accurately (Column 4, lines 39-45)." Moreover, MPEP 2111 states, "Claims must be given their broadest reasonable interpretation. During patent examination, the pending claims must be "given the broadest reasonable interpretation consistent with the specification". Applicant always has the opportunity to amend the claims during prosecution and broad interpretation by the examiner reduces the possibility that the claim, once issued, will be interpreted more broadly than it is justified. *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-51 (CCPA 1969)". In this case, any single particle (as suggested by Schalkhammer that changing the number or size of the

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metal particles are nothing but routine optimization) under any suitable condition can be used to detect a biomolecule.

In view of the response to argument, 102(b) rejection is hereby maintained properly.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CAR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119. The fax phone number for this Group is (703) 872-9306. LIE of this Group Chantae Dessau can be reached at (703)605-1237.


ARUN K. CHAKRABARTI
PATENT EXAMINER

Arun Chakrabarti,

Patent Examiner,

October 23, 2003


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